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IN THE

# Supreme Court of the United States

MERCK KGAA,

*Petitioner,*

v.

INTEGRA LIFESCIENCES I, LTD., *ET AL.*,

*Respondents.*

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

## Brief of Intellectual Property Professors As *Amici Curiae* in Support of Neither Party

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## INTEREST OF THE AMICI CURIAE

This brief is submitted on behalf of Professors Rochelle Dreyfuss, John Duffy, Arti Rai, and Katherine Strandburg, all of whom teach and write in the area of patent law.[1] As teachers and scholars of patent law, the amici are interested in the proper application of the patent law to promote its constitutional purpose of promoting scientific and technological progress. The authors of this brief have no financial interest in this case.

## SUMMARY OF ARGUMENT

The Court has granted certiorari in this case to examine the scope of § 271(e)(1) of the Patent Act, which provides that certain research activities "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs," do not constitute patent infringement. 35 U.S.C. § 271(e)(1). Section 271(e)(1) was enacted in response to a 1984 ruling by the Federal Circuit that the traditional experimental use exemption did not preclude infringement liability for activities undertaken to satisfy the regulatory requirements of the Food, Drug and Cosmetics Act. *Roche Prods. v. Bolar Pharms. Co.*, 733 F.2d 858 (Fed. Cir. 1984). Thus, there is a certain historical connection between the traditional experimental use exemption and the genesis of § 271(e)(1). In her concurring and dissenting opinion below, Judge Newman argued that § 271(e)(1) should be interpreted as a complement of the traditional experimental use exemption so that there would be no "intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity."

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[1] Pursuant to Sup. Ct. R. 37.6, the amici represent that they have authored this brief in whole, and that no person or entity other than the amici and their respective educational institutions has made a monetary contribution to the preparation or submission of the brief. The parties to this case have consented to the filing of this brief, and their written consents have been filed with the clerk of the Court.

*Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 877 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part).

The purpose of this amicus brief is to demonstrate that, despite the historical connections, this Court need not -- and should not -- determine the appropriate reach of the traditional experimental use exemption in considering this case. Section 271(e)(1) and the traditional experimental use exemption are of independent scope and stem from independent policy concerns. The scope of the traditional experimental use exemption is also not fairly included within the question presented to the Court and is of such importance that it should be considered in depth on its own merits.

Furthermore, the amici contend that, because of its unique institutional relationship with the Federal Circuit, this Court should state explicitly that its opinion in the current case does not foreclose future reliance on the traditional experimental use exemption, or on other doctrines limiting infringement liability. Most patent appeals are channeled into the Federal Circuit; that court has sometimes strained to use this Court's few patent opinions as guidance in deciding issues only tangentially related to the questions presented in those cases. As this Court now typically grants certiorari relatively rarely in patent cases (averaging roughly a case a Term), misinterpretations of this Court's patent opinions by a single circuit panel can be costly (because all cases are subject to the misinterpretation) and difficult to correct (because no circuit split develops on the issue). Thus, institutional considerations suggest that this Court should be especially clear in defining the limits of the decision in this case.



## ARGUMENT

### I. The Scope of Section 271(e)(1) of the Patent Act May Be Determined Without Deciding the Scope of the Traditional Experimental Use Exemption under Section 271(a).

Section 271(e)(1) of the Patent Act was enacted in response to the Federal Circuit's determination, in *Roche Products v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984), that certain pharmaceutical testing aimed at producing data required for approval of a generic drug by the federal Food and Drug Administration (FDA) was not exempted from liability under the traditional experimental use exemption.

In response to *Roche*, Congress enacted § 271(e)(1), which states in relevant part:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

35 U.S.C. § 271(e)(1). As explained by this Court in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990), the purpose of the section was to respond to "unintended distortions of the [then] 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." Section 271(e)(1) thus deals with an issue of patent term that arises in a particular regulatory context and, not surprisingly, exempts specific activities that are "reasonably related" to compliance with those regulations.

The traditional experimental use exemption implied under the § 271(a) infringement provision, 35 U.S.C. § 271(a), is of entirely different provenance. As discussed further below, it exempts certain experimental uses from infringement liability because of the essential contribution those activities make to the "Progress of . . . useful Arts." U.S. Const. art. I, § 8, cl. 8. The traditional experimental use exemption plays a significant role in promoting innovation in all areas of science and technology regardless of whether those areas bear any relationship to a "law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1).

In her opinion concurring in part and dissenting in part in this case below, Judge Newman opines that the traditional experimental use exemption should work together with the § 271(e)(1) exemption in cases such as the current one, so that the entire line of research pursued by Merck and its agents "was either exempt exploratory research or was immunized by § 271(e)(1)." *Integra*, 331 F.3d at 877 (Newman, J., concurring in part and dissenting in part). She contends that "[i]t would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity [§ 271(e)(1)], where the patent is infringed and the activity can be prohibited." *Id.*

While Judge Newman's formulation of the case may make it appear that the two exemptions must be interpreted in light of one another, the amici agree with the majority opinion on this point: the traditional exemption "is not before the court in the instant case." *Id.* at 863 n.2. We do not believe that there is any generally applicable relationship between the coverage of the two exemptions. In the case at hand, the two exemptions may well overlap. In other cases, perhaps involving patented research tools, there might be a gap in coverage. Clearly, the statutory exemption does not cover the



vast areas of research in which the regulation of drugs is not at issue. The distinct policies underlying the two exemptions thus require separate analysis. In particular, and of relevance to the Court's consideration of the question presented in this case, it is very important to prevent an expansive interpretation of § 271(e)(1) from being taken to imply a narrow scope for the traditional exemption.

## II. The Traditional Experimental Use Exemption Plays a Vital Role in Ensuring Scientific and Technological Progress.

The traditional experimental use exemption has its origins in the jurisprudence of Justice Story nearly two centuries ago. *See Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600); *Sawin v. Gould*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391). It recognizes the critical role that experimentation plays in technological development by permitting certain unauthorized uses of patented inventions that promote the goals of the patent system. The goals of the exemption are two-fold: to permit experimentation aimed at effectuating the patent disclosure by exploring the properties of the patented invention (sometimes termed "experimenting on" the invention) and to exempt certain basic research uses ("philosophical experiments" in Justice Story's parlance) from liability. Though the history of the traditional exemption is long, its judicial interpretation has been rather sparse prior to recent Federal Circuit consideration of the doctrine. In particular, the courts have yet to consider the scope of the "experimenting on" prong of the traditional exemption, attention in cases thus far having focused on defining the range of "philosophical experiments" to be covered.

The paucity of judicial treatments of the traditional experimental use exemption should not be taken as evidence of

its insignificance. Rather, the traditional exemption has played a significant, though unobtrusive, role in technological progress and was an unchallenged norm on which the scientific community relied. For this reason, the Federal Circuit's recent movement to narrow the traditional exemption has been met with considerable concern by the research community, by members of the intellectual property bar, and by legal academic commentators.

**A. The Traditional Experimental Use Exemption Effectuates the Patent Disclosure Requirement and Fosters Basic Research**

As the Federal Circuit has acknowledged, "the word 'use' in [the patent infringement statute] has never been taken to its utmost possible scope." *Roche*, 733 F.2d at 861. Indeed, the patent law has long recognized limitations on the scope of "use" not only in the infringement context, but also in interpreting other provisions of the Patent Act.

As this Court recently recognized in *Pfaff v. Wells Electronics, Inc.* 525 U.S. 55, 64-65 (1998), "[t]he law has long recognized the distinction between inventions put to experimental use and products sold commercially." In *Pfaff*, the Court considered the scope of § 102(b) of the Patent Act, which bars an inventor from patenting if the invention was "in public use or on sale in this country" more than one year prior to the filing of the patent application. 35 U.S.C. § 102(b). In interpreting that section, the *Pfaff* Court reiterated its longstanding assessment that experimental uses do not constitute "use" under § 102(b) if they encompass "a bona fide effort to bring [the inventor's] invention to perfection, or to ascertain whether it will answer the purpose intended." *Id., quoting City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877). This interpretation of the Patent Act has



remained constant for over a century and, as the *Pfaff* Court noted, "[t]he experimental use doctrine ... has not generated concerns about indefiniteness." *Pfaff*, 525 U.S. at 67. The interpretation serves to balance the rights of the inventor and the rights of the public by permitting inventors to experiment on their inventions without triggering the onset of the limited grace period of § 102(b) of the Patent Act.

Interpreting the word "use" in the infringement provisions also to exclude experimental uses is consistent with the "normal rule of statutory construction" that "identical words used in different parts of the same act are intended to have the same meaning." *Sorenson v. Sec'y of Treasury*, 475 U.S. 851, 860 (1986) (internal quotation marks omitted); *see also Barnhart v. Walton*, 535 U.S. 212, 221 (2002) (also applying this canon of construction). While this canon of statutory construction can be overcome with evidence of contrary intent, here no such evidence exists and, moreover, applying a similar interpretation to restrict the category of infringing "uses" makes sense in light of the policies of the Patent Act. As explained in Judge Newman's opinion in this case, experimentation is needed to fully understand and improve upon the patented invention. *Integra*, 331 F.3d at 875-76 (Newman, J., concurring in part and dissenting in part). Thus, just as permitting inventors to learn more about their inventions before they are required to apply for a patent was held by this Court to be a necessary limitation on the scope of "use" in § 102(b), permitting others to engage in research after the patent is granted is crucial to effectuating the social bargain underlying the grant of a patent. As Judge Newman explained:

> Today's accelerated technological advance is based in large part on knowledge of the details of patented inventions and how they are made and used. Prohibition

> of research into such knowledge cannot be squared with the framework of the patent law.

*Id.* at 875.

Worrisomely, however, beginning in 1984 with the *Roche* decision, the Federal Circuit has narrowed the scope of the traditional experimental use exemption significantly. In *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000), the court held that tests conducted to design around the patented invention constituted infringement, and in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003), it held that the exemption did not apply to a university because the research in question was part of the university's "legitimate business" of "educating and enlightening students and faculty." *Id.* at 1362. The *Madey* opinion thus contained language that could support an interpretation of the traditional exemption that would "produce the anomalous and untenable result of subjecting research institutions to a *disfavored* status under the experimental use defense." Brief of the United States as Amicus Curiae on Petition for Certiorari at 10, *Duke Univ. v. Madey*, No. 02-1007.

Should the Federal Circuit continue along its path of confining the traditional experimental use exemption to those rare occasions on which non-commercial, "philosophical experiments" are undertaken by a party not engaged in the "legitimate business" of such experimentation, the power of the patent system to promote the progress of science and technology will suffer.

The danger is particularly great if the ability of researchers to "experiment on" a patented invention to understand, modify, or improve upon that invention is



curtailed. The patent system requires extensive disclosure of patented inventions as a *quid pro quo* for the grant of the exclusive right. *See* 35 U.S.C. § 112 ("patent specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art . . . to make and use [it] . . ."). Experimentation "on" a patented invention is often a necessary part of fully understanding the disclosure, comprehending the principles underlying the invention, and building upon it. The verbal specification alone is insufficient.

The inadequacy of verbal description to convey technical matters fully has been noted by this Court in other contexts. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731-32 (2002) (acknowledging limitations of language as a justification for the doctrine of equivalents). It is also recognized in the enablement doctrine of undue experimentation, which finds a specification adequately enabling even when some experimentation on the part of the skilled reader is required to "make and use" the invention. *See, e.g., In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

As Judge Newman explained in her opinion below:

> Such detail[ed disclosure] would be idle and purposeless if this information cannot be used for 17-20 years. Indeed, there would be little value in the requirement of the patent law that patented information must be removed from secrecy in consideration of the patent right to exclude, if the information is then placed on ice and protected from further study and research investigation. To the contrary, the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or

improvement. Such activities are integral to the advance of technology.

*Integra*, 331 F.3d at 875 (Newman, J., concurring in part and dissenting in part).

The traditional experimental use exemption also plays a role in preserving the leadership of the United States in scientific and technological progress worldwide. Many other nations have exempted research uses of patented inventions -- especially those aimed at "experimenting on" the invention -- from infringement liability.[2] An overly narrow reading of the traditional experimental use exemption may provide incentives for "outsourcing" research activities to one of these countries. *See* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 Berkeley Tech. L. J. 685, 718-19 (2002) (making this point).

**B. An Overly Narrow Interpretation of the Traditional Experimental Use Exemption Threatens to Upset Longstanding Practices of the Research Community**

The relative paucity of case law explicating the traditional experimental use exemption does not indicate that the exemption is unimportant. Rather, the exemption, particularly as related to "experimenting on" a patented invention and to academic research, formed part of the standard operating procedure of the research community. It is, as Judge Newman put it in her opinion below, "how the patent system has always worked." *Integra*, 331 F.3d at 876 (Newman, J., concurring in

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[2] *See* discussion of foreign exemptions in National Research Council of the National Academies of Sciences, *A Patent System for the 21st Century* (Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, eds., 2004) (hereinafter "NAS Report") at 111-12.



part and dissenting in part). The Federal Circuit's recent narrowing trend has thus been met with consternation by researchers, the intellectual property bar, and intellectual property scholars. A report published by the National Research Council of the National Academies of Sciences selected "Shield[ing] some research uses of patented inventions from infringement liability" as one of seven "Recommendations for a 21st - Century Patent System" in a recent review. NAS Report at 7. It noted in particular that narrowing the exemption for "experimenting on" a patented invention would represent "a fairly radical change in patent law." *Id.* at 110.

The National Academies of Sciences Report noted that the traditional exemption was "widely assumed, especially by academic investigators and research administrators, to shield scientific investigation at universities from lawsuits." *Id.* at 109. It also cited an empirical investigation, undertaken before the issuance of the *Madey* decision, which found that many university and corporate respondents make frequent use of patented inventions in research "on the presumption that research is legally shielded from infringement liability by a 'research exception.'" *Id.* at 72, *citing* John P. Walsh, Ashish Arora, and Wesley M. Cohen, *Research Tool Patents and Licensing and Biomedical Innovation, in Patents in the Knowledge-Based Economy* (Wesley M. Cohen and Stephen A. Merrill, eds., 2003).

Other organizations have also reacted with concern to the perceived shrinking of the traditional experimental use exemption. For example, the American Association for the Advancement of Science, one of the premier scientific research associations, has convened a Research Exemption Working Group. *See* http://sippi.aaas.org/rschexemption.shtml. The organization's background description of the group notes that "[u]ntil recently, it had been assumed that an experimental use

exception exists for purely scientific research to study and understand a patented invention. Many researchers still assume their work is immune from infringement litigation. . . . The U.S. scientific and academic communities are concerned that the [*Madey*] ruling may have a chilling effect on their research . . . ." *Id.*

Finally, numerous legal scholars have written articles expressing concern about the possible impact on future innovation of a vanishing experimental use exemption. *See, e.g.*, Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 Wis. L. Rev. 81 (2004); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457 (2004); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 17 (2001); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Colum. L. Rev. 1177, 1205 (2000); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017 (1989).

The traditional experimental use exemption thus serves two important public purposes, effectuating the patent disclosure bargain and protecting certain basic research. These two purposes are additional to and independent of the policy behind the § 271(e)(1) regulatory exemption. Whatever the Court determines about the scope of § 271(e)(1), the scope of the traditional experimental use exemption should be reserved for decision another day.



**III. The Court Should Clarify that its Interpretation of Section 271(e)(1) in this Case Does Not Foreclose Assertion of the Traditional Experimental Use Exemption**

The procedural posture of this case is complex, and the case is not a good vehicle for making sweeping pronouncements on the relation between patent law and research policy generally. Indeed, even with respect to the § 271(e)(1) issue, the Solicitor General noted in his amicus brief at the certiorari stage that the case is "not an ideal vehicle." Brief for the United States as Amicus Curiae on Petition for Writ of Certiorari in this case at 8.

One of the limitations of this case is that, although the traditional experimental use exemption was applied by the district court to preclude liability for some allegedly infringing activities, *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 96CV1307-B(AJB), 2004 U.S. Dist. LEXIS 20725 (S.D. Cal. September 7, 2004) at *17 - *18, the Petitioner has not pursued the traditional exemption as a defense to the infringement liability at issue here. Thus, the applicability of the traditional experimental use exemption was not briefed or argued to the Court of Appeals and has not been raised by the question presented for certiorari here. The case therefore does not provide a good opportunity for the Court to determine the reach of the traditional experimental use exemption. There are, however, important reasons for the Court to state *explicitly* that any decision in this case does not foreclose the assertion of the traditional experimental use exemption.

First, although the scope of the traditional experimental use exemption is not at issue here, Judge Newman's opinion below suggests that the possibility of a gap in coverage between the traditional experimental use exemption and the regulatory exemption of § 271(e)(1) presents an important policy question

for medical and pharmaceutical research. *Integra*, 331 F.3d at 877 (Newman, J., concurring in part and dissenting in part). That line of reasoning could suggest, though this is certainly not Judge Newman's position, that an expansive interpretation of § 271(e)(1) would confine the scope of or mitigate the need for the traditional experimental use exemption. Because the traditional exemption applies to all areas of technology and has different policy bases from the § 271(e)(1) regulatory exemption, such a conclusion is unwarranted.

We recognize that Judge Newman may have been motivated to include the common law exemption in the case because a side effect of specialized appellate litigation is that once an issue is decided by the Federal Circuit, it cannot be easily re-litigated by other parties or brought by them to the Supreme Court for review. In principle, of course, the applicability of the traditional experimental use exemption could be raised in another case, even in one that is factually identical to some previous case in which the Federal Circuit has rejected an experimental use defense, because the scope of the exemption is an issue of law that has not been considered by this Court. *See Duke Univ. v. Madey*, 539 U.S. 958 (2003) (denying certiorari). However, as a practical matter, counsel may be reluctant to do so. They may reasonably fear that persisting with the traditional experimental use exemption argument will impair their credibility and jeopardize the appellate court's perception of the client's entire case.

Like many courts, the Federal Circuit has sent unmistakable signals that it does not appreciate litigants raising issues that have been resolved by Federal Circuit precedent even in cases where conflicting authority exists and the issue has not been decided by this Court. For example, in *Allen Engineering Corp. v. Bartell Industries*, 299 F.3d 1336, 1356 (Fed. Cir. 2002), the Federal Circuit explicitly chastised



counsel for "obfuscation, deflection and mischaracterization" because counsel had cited patent precedents from the Fifth Circuit with which the Federal Circuit disagreed. *See also London v. Carson Pirie Scott & Co*, 946 F.2d 1534, 1538 (Fed. Cir. 1991) (disparaging the doctrine of equivalents as the "second prong" of every infringement suit).

This type of reaction is not unique to the Federal Circuit. Other circuits have also sometimes shown their displeasure with litigants who preserve arguments foreclosed by circuit authority. For example, in *McKnight v. General Motors Corp.*, 511 U.S. 659 (1994), the Seventh Circuit had imposed a $500 sanction on an attorney whose appeal was based on an argument that had been rejected by the circuit court, but that had divided district courts. Though this Court reversed the sanction in a unanimous *per curiam* opinion, the Seventh Circuit's action is a rather extreme example of a natural and common tendency for courts to be somewhat displeased with litigants who challenge a court's own precedents. That tendency may have only modest effects where many circuits confront the same legal issues, but it is of much greater moment in areas in which a single intermediate appellate court has a near monopoly over interpretation of the law.

When there are several appellate channels, an issue decided by one court can be litigated in other circuits without raising the ire of the judges. Further, a substantial diversity of views among jurists is likely to lead to diverse outcomes, facilitating both the evolution of circuit court positions and the positioning of issues for review by this Court. *Cf. United States v. Stauffer Chem. Co.*, 464 U.S. 165 (1984) (estopping the U.S. from re-litigating the identical issue against the same litigant, on the theory that there are other ways to obtain judicial reconsideration of an issue). When there is a single

appellate tribunal, significant controversy may remain undeveloped. However, the solution to this problem is not to shoehorn an issue into a case where there is an insufficient record to decide it properly. Rather, the Court should clarify that the scope of the traditional experimental use exemption is an issue that remains open and can be asserted in appropriate cases.

There is another reason why the Court should specifically state that this case does not affect the vitality or scope of the traditional experimental use exemption. Because patent appeals have largely been centralized within the Federal Circuit, there is less need to review Federal Circuit patent cases for uniformity reasons. With few cases decided by the Supreme Court, the Federal Circuit has strained to find guidance in every decision. For example, in a concurring opinion in *Embrex,* Judge Rader argued that this Court's precedent has *already* eliminated the traditional experimental use defense:

> Turning next to the experimental use excuse, neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity. Rather, the Supreme Court and this court have recently reiterated that intent is irrelevant to infringement. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 34, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.") ...



> These recent pronouncements should dispose of the intent-based prong of [the appellant's] argument.

*Embrex,* 216 F.3d at 1353 (Rader, J., concurring). Yet *Warner-Jenkinson* was a case about the doctrine of equivalents; nothing in the facts, arguments, or lower court decision raised a question about experimental use.

Similarly in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 234 F.3d 558, 576 (Fed. Cir. 2000), where the Federal Circuit had created the so-called "complete bar" rule of prosecution history estoppel, the Federal Circuit believed that it was following the implications of certain dicta from this Court's then recent decision in *Warner-Jenkinson. See Festo,* 234 F.3d at 576 (claiming that the "Supreme Court recognized the value of a complete bar in *Warner-Jenkinson* when it discussed the presumption that prosecution history estoppel applies when an amendment is unexplained"). Nevertheless, this Court reversed unanimously, finding that the Federal Circuit "ignored the guidance of *Warner-Jenkinson,* which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo* 535 U.S. at 739. History thus suggests that an explicit instruction on the reach of the decision in this case would be helpful to make clear the limits of the Court's ruling in this case and to prevent any possible misinterpretation concerning the scope of the narrow statutory issues presented here.

## CONCLUSION

For the foregoing reasons, the Court should state explicitly that its ruling in this case does not foreclose later consideration of the scope of the traditional experimental use exemption and that the reach of that exemption, especially in the "experimenting on" context, is not limited by the scope of § 271(e)(1). Should the Court decide to consider the traditional experimental use exemption in its determination of this case, amici respectfully request that the Court provide an opportunity for further briefing of the issue.

Respectfully submitted,

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